Exhibit 3a

K062538

DIACARE CORP.

4977 E. La Palma Ave.
Anaheim, CA 92807
Tel:(714) 970-7289

APR 30 2007

510(k) Summary

Administrative Information and Device Identification

Name and address of sponsor of the 510(k) submission:		Diacare Corp. 4977 E. LA PALMA AVE. ANAHEIM, CA 92807
Official contact person for all correspondence:		Calvin Chang, calvin@evermed.com Phone: (714) 970-7289; Fax: (714) 777-9978
Date Prepared:		August 21, 2006
Device Name:		EASY CHECK Blood Glucose Monitoring System
Generic name of the device:		Blood Glucose Meter
Classification of new device:		Class II
Classification Panel:		Clinical Chemistry and Toxicology
Product Code and CFR Regulation Number:		NBW, CGA and 21 CFR 862.1345
Predicate Device Name and 510(k) Number:		ASCENSIA ELITE DIABETES CARE SYSTEM k043311

Description of Device:

The EASY CHECK Blood Glucose Monitoring System is designed to provide an easy, accurate method for determining capillary blood glucose values. This analysis is based on amperometric technology using glucose oxidase that is specific for the blood glucose measurement. When the blood sample is applied to the test strip, electrons are formed by the reaction between glucose oxidase and blood glucose. The electrical current is measured by the meter and correlates with the concentration of glucose in the blood sample.

The EASY CHECK Blood Glucose Monitoring System consists of the Meter, Test strips with instructions, Lancing device with instructions, Lancets, Code card, 3-Volt Lithium Coin Battery, Users Guide, Log Book, Carrying case and EASY CHECK Control Solutions (level 1 and level 2)

Comparison of Device Technological Characteristics to Predicate Device:

EASY CHECK Blood Glucose Monitoring System and ASCENSIA ELITE DIABETES CARE SYSTEM are similar in many respects. Among other similarities, they use the same detection method, enzyme, mediator and basic electrode material.

Differences include the Hematocrit range, temperature range, test time and sample volume. Tests included in this 510(k) submission have incorporated these changes and results show that they introduce no new questions on the safety and effectiveness of the EASY CHECK Blood Glucose Monitoring System.

Similarities:

Item	Device	Predicate
	Easycheck	Bayer Elite
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase
Mediator	Potassium Hexacyanoferrate	Potassium Hexacyanoferrate
Electrode	Carbon	Carbon
Coding	Code key	Code Key
Sample type	whole blood	whole blood
Humidity	20%-80%	20%-80%

Power Supply	3V lithium battery (CR2032)	3V lithium battery (CR2032)
Battery lifetime	Over 1000 tests	Over 1000 tests
Weight	50 g	50 g

Differences:

Temp. Range	2-30 □ 36-86 □	15-30 □ 60-86 □
Hct Range	30%-50%	20%-60%
Test Range	30-600 mg/dL	20-600 mg/dL
Test time	9 second	30 second
Sample volume	1.5 □L	3 □L
Test sample	fingertip, palm and forearm	fingertip
Memory	180 sets	20 sets
Meter dimension	58x80x19 mm	81x51x14 mm

Intended Use:

The EASY CHECK Blood Glucose Monitoring Systems is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the following alternative sites: the palm and the forearm. It is intended for use by healthcare professionals and people with diabetes mellitus at home and healthcare facilities as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Non-Clinical Testing:

Sensitivity, precision, linearity and other tests were used to demonstrate the performance and reliability of EASY CHECK Blood Glucose Monitoring System. Meter also passed appropriate EMC requirements.

Clinical Testing:

Consumer (field) testing was done to prove that the EASY CHECK Blood Glucose Monitoring System is easy to use by lay people and also that test results are accurate and comparable to a laboratory reference method and to the predicate device.

Conclusion:

Detailed testing has confirmed that the EASY CHECK Blood Glucose Monitoring System is substantially equivalent to the predicate device and that the differences do not bring up any new safety or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Diacare Corp.
c/o Mr. Sid Mathur
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

APR 3 0 2007

Re: k062538
Trade/Device Name: Easy Check Blood Glucose Monitoring System and Easy Check Glucose Control Solution
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: April 2, 2007
Received: April 3, 2007

Dear Mr. Mathur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), and Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062538

Device Name: **EASY CHECK Blood Glucose Monitoring System**

Indications for Use: The EASY CHECK Blood Glucose Monitoring Systems is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the following alternative sites: the palm and the forearm. It is intended for use by healthcare professionals and people with diabetes mellitus at home and healthcare facilities as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Prescription Use ✓ AND/OR Over-The-Counter Use ___*___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062538

Indications for Use

510(k) Number (if known): K062538

Device Name: **EASY CHECK Glucose Control Solution**

Indications for Use: The EASY CHECK Control Solution is intended for in vitro diagnostic use by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the EASY CHECK Blood Glucose Monitor System.

Prescription Use ___✓___ AND/OR Over-The-Counter Use ___*____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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...ffice of In Vitro Diagnostic Device
Evaluation and Safety

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